

## Global Head Sterility Assurance

Job ID  
REQ-10080057

6月 05, 2026

Austria

### 摘要

The Global Head Sterility Assurance provides strategic leadership for sterility assurance and aseptic quality across the Novartis manufacturing network. This role leads Quality Assurance leaders and Senior Global Aseptic Processing Experts to ensure aseptic operations comply with cGMP requirements, health authority regulations, and Novartis Quality Manual and Policy standards.

The role oversees sterility assurance performance across approximately 20-30 aseptic manufacturing sites, including Large Molecules, Aseptics, Advanced Therapies, and Radioligand Therapy platforms. It drives alignment, communication, inspection readiness, and sustainable compliance across the network.

Key responsibilities include ensuring readiness for FDA and other health authority inspections, supporting compliance with evolving GMP expectations such as EU GMP Annex 1, tracking remediation actions, and preventing repeat observations. In partnership with Technical Operations and site Quality teams, the role also supports quality programs, aseptic project metrics, documentation standards, and continuous improvement initiatives.

This position is central to harmonizing sterility assurance practices, strengthening quality culture, and

advancing patient safety and operational excellence across the global aseptic network.

## About the Role

This role requires global travel of up to 30-35%.

Deadline for applications: 19th of June 2026.

### Major Accountabilities:

- Lead the global aseptic processing function across sites and manufacturing platforms with aseptic operations.
- Drive, support, and oversee global aseptic initiatives, including process optimization across the Novartis manufacturing network.
- Ensure site readiness for Health Authority and GGA inspections through effective preparation, support, and follow-up.
- Monitor timely execution and closure of quality actions and remediation plans in line with required timelines.
- Oversee aseptic operations in new production facilities and microbiology laboratories.
- Provide microbiology subject matter expertise and support escalation management for contamination, sterility, and related quality issues.
- Promote best-practice sharing, cross-platform communication, and consistent resolution of technical and quality issues in line with global cGMP standards, including Annex 1.
- Manage aseptic KPI trending, sterility assurance governance, expert networks, training programs, and development of aseptic experts across sites and global functions.

### Obligatory requirements:

- Graduate degree in Chemistry, Pharmacy, Microbiology, or a related scientific discipline; Ph.D. or advanced degree preferred.
- 10-15 years of pharmaceutical industry experience, including senior management or leadership roles in Quality Assurance, Quality Operations, Compliance, or global/site quality functions.
- Strong experience in pharmaceutical manufacturing, preferably within an FDA-regulated and global cGMP environment.
- In-depth knowledge of cGMP requirements across the US and EU, including self-inspections, third-party audits, deviation and complaint management, GMP training, and SOP systems.
- Deep technical understanding of microbiology, sterility assurance, and aseptic processing.
- Proven people leadership, stakeholder management, negotiation, communication, and escalation skills across diverse global teams and functions.
- Strong project management experience, with the ability to lead complex cross-functional and global initiatives.
- Fluent English communication skills, both written and spoken.

Why Novartis? Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more

here: <https://www.novartis.com/about/strategy/people-and-culture>

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部门

Operations

Business Unit

Quality

地点

Austria

站点

Schaftenau

Company / Legal Entity

AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH

Alternative Location 1

Barcelona Gran V í a, Spain

Alternative Location 2

Morris Plains, New Jersey, USA

Alternative Location 3

Puurs, Belgium

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

```
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showSpeedMenu: false }, css : "/modules/custom/arcticnckalturaaddon/css/kalturavideo.css",
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false, playlistEvents: false, castEvents: false } }; }
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media. kalturaPlayer.loadMedia({entryId: "1_dgfvmafo"}); } catch (e) { console.error(e.message) }
```

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1. <https://www.novartis.com/about/strategy/people-and-culture>
2. <https://www.novartis.com/about/strategy/people-and-culture>
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